

What is claimed is:

1. A method of predicting subject noncompliance, comprising the steps of:
providing historical subject compliance data;
5 generating at least one predictive algorithm for predicting subject
noncompliance by quantitative analysis of the historical subject compliance; and
translating the at least one predictive algorithm into at least one prediction rule
for use with a clinical trial.
- 10 2. The method of predicting subject noncompliance of claim 1, further
comprising the steps of:
obtaining subject compliance information; and
comparing the subject compliance information to the at least one prediction
rule to determine if action is needed.
- 15 3. The method of predicting subject noncompliance of claim 1, wherein said step
of providing includes providing historical protocol data and wherein said step of
generating includes quantitative analysis of the historical protocol data.
- 20 4. The method of predicting subject noncompliance of claim 2, further
comprising the step of determining an appropriate action if the step of comparing
indicates that action is needed.
5. The method of predicting subject noncompliance of claim 2, wherein the step
25 of obtaining includes the step of employing a portable electronic device capable of
displaying information and receiving and storing input from a user.
6. The method of predicting subject noncompliance of claim 2, further
comprising the step of creating an evaluability database adapted to store data related to
30 subject compliance.
7. The method of predicting subject noncompliance of claim 6, wherein the
evaluability database is tailored to a condition affecting the subject.

8. The method of determining subject noncompliance of claim 1, wherein the step of providing employs at least one database containing at least one of the group of the historical subject compliance data and the historical protocol data.

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9. A method of determining subject noncompliance, comprising the steps of:
providing at least one of the group of historical subject compliance data and historical protocol data;

generating at least one algorithm reflective of at least one of the group of the
10 historical subject compliance data and the historical protocol data by quantitative analysis of the historical subject compliance data and the historical protocol data;

translating the at least one algorithm into at least one decision rule for analyzing subject compliance information;

obtaining the subject compliance information; and
15 comparing the subject compliance information to the at least one decision rule to determine if corrective action is needed.

10. The method of determining subject noncompliance of claim 9, further comprising the step of determining an appropriate corrective action if the step of
20 comparing indicates that corrective action is needed.

11. The method of determining subject noncompliance of claim 9, wherein the step of obtaining includes using a portable electronic device capable of displaying information and receiving and storing input from a user.

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12. The method of determining subject noncompliance of claim 9, wherein the step of generating employs at least one of the group of multiple linear regression, discriminant function analysis, logistic regression, neural networks, classification trees and regression trees.

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13. The method of determining subject noncompliance of claim 9, wherein the step of providing employs at least one database containing at least one of the group of the historical subject compliance data and the historical protocol data.

14. A method of determining subject noncompliance, comprising the steps of:
providing historical subject compliance data and historical protocol data;
generating a spectrum of noncompliance representative of the historical subject
5 compliance data not compliant with the historical protocol data by quantitative
analysis of the historical subject compliance data and the historical protocol data;
obtaining subject compliance information; and
comparing the spectrum of noncompliance to the subject compliance
information to determine if corrective action is needed.
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15. The method of determining subject noncompliance of claim 14, further
comprising the step of determining an appropriate corrective action if the step of
comparing indicates that corrective action is needed.
- 15 16. The method of determining subject noncompliance of claim 15, wherein the
step of obtaining includes using a portable electronic device capable of displaying
information and receiving and storing input from a user.
17. A method of detecting subject fraud, comprising the steps of:
20 providing historical subject compliance data and historical protocol data;
generating at least one fraud detection algorithm for detecting subject fraud by
quantitative analysis of the historical subject compliance data and the historical
protocol data; and
translating the at least one fraud detection algorithm into at least one fraud
25 detection rule for use with a clinical trial.
18. A method of detecting subject fraud, comprising the steps of:
providing subject compliance data;
generating at least one fraud detection algorithm for detecting subject fraud by
30 quantitative analysis of the compliance data; and
translating the at least one fraud detection algorithm into at least one fraud
detection rule for use with a clinical trial.

19. The method of detecting subject fraud of claim 18, further comprising the steps of:

comparing the subject compliance information to the at least one fraud detection rule to determine if action is needed.

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20. The method of detecting subject fraud of claim 19, further comprising the step of determining an appropriate action if the step of comparing indicates that action is needed.

10 21. The method of detecting subject fraud of claim 19, wherein the step of providing includes the use of a portable electronic device capable of displaying information and receiving and storing input from a user.

22. The method of detecting subject fraud of claim 19, further comprising the step
15 of creating an evaluability database adapted to store data related to subject fraud.

23. The method of detecting subject fraud of claim 22, wherein the evaluability database is tailored to a condition affecting the subject.

20 24. The method of detecting subject fraud of claim 18, wherein the step of providing employs at least one database containing at least one of the group of the historical subject compliance data and the historical protocol data.

25 25. A medium suitable for use in an electronic device and having instructions for execution on the electronic device, the instructions comprising the steps of:

providing at least one of the group of historical subject compliance data and historical protocol data;

generating at least one predictive algorithm for predicting subject noncompliance by quantitative analysis of at least one of the group of the historical
30 subject compliance data and the historical protocol data; and

translating the at least one predictive algorithm into at least one prediction rule for use with a clinical trial.

26. The medium of claim 25 having instructions further comprising the steps of:
obtaining subject compliance information; and
comparing the subject compliance information to the at least one prediction
rule to determine if action is needed.

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27. The medium of claim 25, wherein the step of obtaining includes the use of a
portable electronic device capable of displaying information and receiving and storing
input from a user.

10 28. The medium of claim 25 having instructions further comprising the step of
creating an evaluability database adapted to store data related to subject compliance.

29. A medium suitable for use in an electronic device and having instructions for
execution on the electronic device, the instructions comprising the steps of:

15 providing at least one of the group of historical subject compliance data and
historical protocol data;

generating at least one algorithm reflective of at least one of the group of the
historical subject compliance data and the historical protocol data by quantitative
analysis of the historical subject compliance data and the historical protocol data;

20 translating the at least one algorithm into at least one decision rule for
analyzing subject compliance information;

obtaining the subject compliance information; and

comparing the subject compliance information to the at least one decision rule
to determine if corrective action is needed.

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30. The medium of claim 29 having instructions further comprising the step of
determining an appropriate corrective action if the step of comparing indicates that
corrective action is needed.

30 31. The medium of claim 29, wherein the step of obtaining includes using a
portable electronic device capable of displaying information and receiving and storing
input from a user.

32. The medium of claim 29, wherein the step of generating employs at least one of the group of multiple linear regression, discriminant function analysis, logistic regression, neural networks, classification trees and regression trees.

5 33. A medium suitable for use in an electronic device and having instructions for execution on the electronic device, the instructions comprising the steps of:
providing historical subject compliance data and historical protocol data;
generating a spectrum of noncompliance representative of the historical subject
compliance data not compliant with the historical protocol data by quantitative
10 analysis of the historical subject compliance data and the historical protocol data;
obtaining subject compliance information; and
comparing the spectrum of noncompliance to the subject compliance
information to determine if corrective action is needed.

15 34. The medium of claim 33 having instructions further comprising the step of determining an appropriate corrective action if the step of comparing indicates that corrective action is needed.

35. The medium of claim 34, wherein the step of obtaining includes using a
20 portable electronic device capable of displaying information and receiving and storing input from a user.

36. A medium suitable for use in an electronic device and having instructions for execution on the electronic device, the instructions comprising the steps of:
25 providing historical subject compliance data and historical protocol data;
generating at least one fraud detection algorithm for detecting subject fraud by quantitative analysis of the historical subject compliance data and the historical protocol data; and
translating the at least one fraud detection algorithm into at least one fraud
30 detection rule for use with a clinical trial.

37. A medium suitable for use in an electronic device and having instructions for execution on the electronic device, the instructions comprising the steps of:

- providing subject compliance data;
 - generating at least one fraud detection algorithm for detecting subject fraud by quantitative analysis of the compliance data; and
 - translating the at least one fraud detection algorithm into at least one fraud
- 5 detection rule for use with a clinical trial.